

Biotechnology Risk Assessment Research Grants Program

FY 2007 Request for Applications

APPLICATION DEADLINE: February 15, 2007



U.S. Department of Agriculture



Cooperative State Research, Education, and Extension Service

**COOPERATIVE STATE RESEARCH, EDUCATION, AND EXTENSION SERVICE;
U.S. DEPARTMENT OF AGRICULTURE**

BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

INITIAL ANNOUNCEMENT

CATALOG OF FEDERAL DOMESTIC ASSISTANCE: This program is listed in the Catalog of Federal Domestic Assistance under 10.219, Biotechnology Risk Assessment Research.

DATES: Applications must be received by Grants.gov by close of business (COB) on **February 15, 2007 (5:00 p.m. Eastern Time)**. Applications received after this deadline will normally not be considered for funding. Comments regarding this request for applications (RFA) are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: The Cooperative State Research, Education, and Extension Service (CSREES) is requesting comments regarding this RFA from any interested party. These comments will be considered in the development of the next RFA for the program, if applicable, and will be used to meet the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). This section requires the Secretary to solicit and consider input on a current RFA from persons who conduct or use agricultural research, education and extension for use in formulating future RFAs for competitive programs. Written stakeholder comments on this RFA should be submitted in accordance with the deadline set forth in the DATES portion of this Notice.

Written stakeholder comments should be submitted by mail to: Policy, Oversight, and Funds Management Branch; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; USDA; STOP 2299; 1400 Independence Avenue, SW; Washington, DC 20250-2299; or via e-mail to: RFP-OEP@csrees.usda.gov. (This e-mail address is intended only for receiving comments regarding this RFA and not requesting information or forms.) In your comments, please state that you are responding to the Biotechnology Risk Assessment Research Grants Program RFA.

EXECUTIVE SUMMARY: CSREES and the Agricultural Research Service (ARS) requests applications for the Biotechnology Risk Assessment Research Grants Program (BRAG) for fiscal year (FY) 2007 to support environmental assessment research concerning the introduction of genetically engineered organisms into the environment. The amount available for support of this program in FY 2007 is approximately \$3.0 million.

This notice identifies the objectives for BRAG projects, the eligibility criteria for projects and applicants, and the application forms and associated instructions needed to apply for a BRAG grant. CSREES additionally requests stakeholder input from any interested party for use in the development of the next RFA for this program.

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PART I—FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority and Background

Authority for the BRAG program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901) (Pub. L. 107-171). In accordance with the legislative authority in the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901), “research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered animals, plants, and microorganisms” will be solicited by the BRAG program. CSREES and ARS of the U.S. Department of Agriculture jointly administer the BRAG program. The administrative regulations for this program are found at 7 CFR 3415.

B. Purpose and Priorities

The purpose of the BRAG program is to assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically modified organisms, including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with scientific information relevant to regulatory considerations derived from the risk assessment research that the program funds.

The BRAG program supports risk assessment research, which is defined as the science-based evaluation and interpretation of factual information in which a given hazard, if any, is identified, and the consequences associated with the hazard are explored. Research funded through this program will be relevant to risk assessment and the regulatory process. When evaluating transgenic organisms, Federal regulators must answer the following four general questions:

1. Is there a hazard (potential hazard identification)?
2. How likely is the hazard to occur (quantifying the probability of occurrence; identifying likely exposure scenarios)?
3. What is the severity and extent of the hazard if it occurs (quantifying the effects)?; and
4. Is there an effect above and beyond what might occur with an organism that has similar traits, but was developed using other technologies?

The BRAG program will also support risk management research, which is defined to include either: (1) research aimed primarily at reducing effects of specific biotechnology-derived agents; or (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the consequences identified in a risk assessment.

Although Project Directors (PDs) are not required to perform actual risk assessments as part of the research they propose, they should design studies that will provide information useful to regulators for making science-based decisions in their assessments of genetically-modified organisms. Accordingly, applicants are encouraged to address the following questions in their applications:

- What is the relevance of this research to the evaluation of transgenic organisms?
- What information will be provided by this research to help regulators adequately assess transgenic organisms?; and
- How does this research model approximate studies necessary to identify and/or characterize hazards associated with introducing genetically modified organisms into the environment?

Applications to the BRAG program must address one of the following program areas or seek partial funding for a conference that addresses science-based risk assessment or risk management of genetically modified organisms released into the environment (See Part I, C. for more detailed descriptions):

1. Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with genetically engineered animals, plants, and microorganisms;
2. Research designed to develop methods to monitor the dispersal of genetically engineered animals, plants, and microorganisms;
3. Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between genetically engineered animals, plants, and microorganisms, and related wild and agricultural organisms;
4. Environmental assessment research designed to provide analysis which compares the relative impacts of animals, plants, and microorganisms modified through genetic engineering to other types of production systems; and
5. Other areas of research designed that further the purposes of the BRAG program.

C. Program Area Description

CSREES and ARS will competitively award research grants to support science-based biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically modified organisms into the environment and helping regulators to develop policies regarding such introduction. In addition, the BRAG program is accepting proposals seeking partial funding for a conference that addresses science-based risk assessment or risk management of genetically modified organisms released into the environment.

Research Proposals

Research proposals must address one of the following five (5) program areas:

1. Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with genetically engineered animals, plants, and microorganisms. Potential areas of research include, but are not limited to:
 - (a) Modeling of management strategies, including models to predict the fate of a transgene if transgenic individuals escape or are released into the environment. Model development should include validation and testing of the model's robustness and predicted outcomes over large temporal-spatial scales, different genetic backgrounds, combinations of confinement methods, size ratio of the transgenic pollen or seed source and the receiving population or border rows, distribution and abundance of pollinators and competing plants, topographic features that limit wind-assisted dispersal, seed loss or dispersal by equipment or other means, etc.;
 - (b) Development of technology, or new deployment methods, to reduce the undesired spread of genetically engineered organisms into natural and managed environments, and to study the stability and efficacy of such methods in field environments;
 - (c) Assessing the effects and effectiveness of reproductive or breeding containment strategies such as sterilization or mono-sexing transgenic animals; and
 - (d) Mitigation steps to limit gene introgression when transgenic animals are released or escape into the environment, physical containment fails, and biological containment is unavailable.
2. Research designed to develop methods to monitor the dispersal of genetically engineered animals, plants, and microorganisms. Potential areas of research include, but are not limited to:
 - (a) Assessing the effects of transgene(s) in engineered animal species that may easily spread and become invasive such as birds, aquatic species, arthropods and other invertebrates (This area includes studies of transgene stability over multiple generations; comparative mating competence or reproductive studies; juvenile and adult viability studies; and comparative behavior and biology studies including studies addressing whether engineering alters host range or ecological interactions);
 - (b) Survivability profiles and/or fitness of transgenic organisms in the wild;
 - (c) Strategies for large-scale deployment or field studies of genetically engineered organisms with special reference to those considerations that may not be revealed through small-scale evaluations and tests; (This component may include methods to extrapolate from laboratory data to field conditions or modeling. Model development should include validation and testing of the model's robustness and predicted outcomes over large temporal-spatial scales, different genetic backgrounds, etc.);

(d) Development of statistical methodologies, and evaluation of current confinement practices, used to field test genetically modified organisms, including those animals and plants that may easily spread and become invasive; and

(e) Development of sensitive methods or tools to predict and monitor distribution of transgenic organisms after release into the environment.

3. Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between genetically engineered animals, plants, and microorganisms, and related wild and agricultural organisms. Potential areas of research include, but are not limited to:

(a) Impacts of gene flow from transgenic crops, insects, animals, or microorganisms to related organisms, communities, or ecosystems; [Gene flow research should be directed to organisms with a high potential for outcrossing to sexually compatible crop species, gene flow to feral or wild relatives, or for gene introgression (e.g., those species with high rates of outcrossing) and to genes that have a high potential for altering the fitness of the recipient organism for its environment. With regard to plants, preference will be given to studies with species that have sexually compatible wild relatives in the United States];

(b) Fate and stability of transgenes that have been introduced by outcrossing into populations of non-transgenic organisms, and the degree to which they confer a selective advantage or disadvantage upon the carriers;

(c) Measuring impact of transgene placement (nuclear or cytoplasmic) on the transfer and introgression of transgenes into wild and feral plants, animals, or fungi especially as a means of confinement;

(d) The rate of transmission of stacked and pyramided genes, including studies on the influence of genetic factors (such as linkage) on the transmission and establishment of multiple genes;

(e) Development of ecologically neutral markers to detect and measure long-distance pollen dispersal and the movement of transgenes and their expression products;

(f) Development of effective genetic containment strategies, and evaluation of the efficacy of genetic techniques, to prevent gene transfer or outcrossing; and

(g) The potential for recombination between viruses in host organisms and host-encoded viral transgenes.

4. Environmental assessment research designed to provide analysis which compares the relative impacts of animals, plants, and microorganisms modified through genetic engineering to other types of production systems. Potential areas of research include, but are not limited to:

- (a) Elucidation of the influence of genetically-engineered crops on ecosystem function through measurement of key ecological processes, including nutrient cycling; decomposition; pollination; regulation of pest populations by parasitoids, predators, or herbivores; etc.;
- (b) Assessment of the relative impacts of agricultural or forest management systems, using transgenic versus non-transgenic organisms, on biodiversity of agro- or forest ecosystems; (Important focus areas are the presence and function of various types of beneficial organisms; defining the magnitude of changes in indicator species or communities that should trigger concerns regarding ecosystem impacts; and how the biology and ecology of indicator taxa are influenced by geography, seasonal fluctuations, crop species, etc.);
- (c) Documentation of significant off-site community or ecosystems effects that are not revealed by studies on small plots (including both beneficial and detrimental effects), such as altered land use practices or other aspects of human ecology, species displacement, soil erosion, water quality, or other geographically dispersed events; (The intent is to learn how the introduction of transgenic organisms alters the impact of agriculture on the rural environment. There is a need to identify appropriate sample size, plot size, study duration, and positive and negative controls, including consideration of specific pesticides in conventional agronomic practices, untreated control plots, or organic production systems.); and
- (d) Comparative management techniques and resources required for maintenance of non-transgenic animals versus transgenic animals (e.g., changes in land use or manure management practices required for transgenic animals engineered to utilize feed more efficiently).

5. Other areas of research designed to further the purposes of the BRAG Program. Potential areas of research include, but are not limited to:

- (a) The potential for unintended effects of introduced foreign gene products; [Such studies may include development of improved methods to assess potential impacts of non-target organisms; direct or indirect (pleiotropic or epistatic) effects of transgenes on host biochemistry or host gene expression where there is reason to expect that changes would significantly affect non-target organisms, etc.]; and
- (b) Assessing the effects of genetically engineered plants with stacked or pyramided resistance genes or multiple genes that confer broad resistance to insects or diseases; (Research focus areas include: the impact of gene stacking on non-target species; the effects of stacked genes on pest populations; and ecological significance and practices needed to address weedy hosts with pest complexes sufficiently variable as to require broad resistance or stacked genes for their control.) Proposals on pest resistance management are not excluded from the program, but any such proposals submitted should describe a significant connection with biotechnology risk assessment in order to differentiate the proposal from product stewardship.

Awards will not be made for food safety risk assessment or risk management, human or animal health risk assessment or risk management, social or economic research, methods

for seed storage, clinical trials, commercial product development, product marketing strategies, product stewardship, marketing or trade issues associated with genetically modified organisms, or other research deemed inappropriate to risk assessment or risk management.

Conference Proposals

Applicants to the BRAG program may request partial funding to organize a conference that brings together scientists, regulators, and other stakeholders to review the science-based data relevant to science-based risk assessment or risk management of genetically modified organisms released into the environment. To be eligible for funding, the steering committee for the proposed conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate.

BRAG conference applications should: 1) describe the relevance of the proposed conference to agricultural biotechnology risk assessment and/or risk management in the United States, 2) explain the uniqueness and timeliness of the conference, 3) outline the qualifications of the organizing committee and the appropriateness of the invited speakers to the topic areas to be covered, 4) state clearly the goals of the conference and the likely outcomes, 5) explain the need for the various elements of the budget, and 6) describe the means by which the organizers will make up the total costs of the conference from other sources.

The goals for the conference should include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings will be required. **In FY 2007, the BRAG program will fund a maximum of two awards for conferences. Each conference award will be limited to a maximum of \$10,000 (total costs).**

PART II—AWARD INFORMATION

A. Available Funding

There is no commitment by USDA to fund any particular application or to make a specific number of awards. Approximately \$3.0 million will be available to fund applications in FY 2007.

B. Types of Applications

In FY 2007, applications may be submitted to the BRAG Program as one of the following four types of requests:

(1) New application. This is a project application that has not been previously submitted to the BRAG Program. All new applications will be reviewed competitively using the selection process and evaluation criteria described in Part V—Application Review Requirements.

(2) Renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in an original or amended award. Applications for renewed funding must contain the same information as required for new applications, and additionally must contain a Progress Report (see Project Narrative, Part IV, B.). Renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(3) Resubmitted application. This is an application that had previously been submitted to the BRAG Program but not funded. Project Directors (PDs) must respond to the previous review panel summary (see Response to Previous Review, Part V., 3.11 of the “CSREES Grants.gov Application Guide: A Guide for Preparation and Submission of CSREES Applications via Grants.gov”). Resubmitted applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(4) Resubmitted renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in the original award. In addition, this is an application that had previously been submitted for renewal to the BRAG Program but not funded. Therefore, PDs must provide a Progress Report as required under the Project Narrative, Part IV, B., and must respond to the previous review panel summary as required under Response to Previous Review, Part V., 3.11 of the “CSREES Grants.gov Application Guide: A Guide for Preparation and Submission of CSREES Applications via Grants.gov”. Resubmitted renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate areas to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

C. Project Types

Research proposal requests should be limited to a total budget of \$400,000 (including indirect costs) for 2-5 years of support. Proposals requesting a total budget of more than \$400,000 (including indirect costs) will be returned to the applicant without review. Funds awarded will not exceed \$400,000. Project periods cannot exceed five years. Conference proposal requests should be limited to a total budget of \$10,000.

The BRAG program will not support applications for Postdoctoral Fellowships.

PART III—ELIGIBILITY INFORMATION

A. Eligible Applicants

Applications may be submitted by any United States public or private research or educational institution or organization. Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project. An applicant's failure to meet an eligibility criterion by the time of an application deadline will result in CSREES returning the application without review or, even though an application may be reviewed, will preclude CSREES from making an award.

B. Cost Sharing or Matching

CSREES does not require matching support for this program and matching resources will not be factored into the review process as evaluation criteria.

PART IV—APPLICATION AND SUBMISSION INFORMATION

A. Address to Request Application Package

Only electronic applications may be submitted via Grants.gov to CSREES in response to this RFA.

Prior to preparing an application, it is suggested that the PD first contact an Authorized Representative (AR) to determine if the organization is prepared to submit electronic applications through Grants.gov. If the organization is not prepared, the AR should see http://www.grants.gov/applicants/get_registered.jsp for steps for preparing to submit applications through Grants.gov. Note, Grants.gov works only with Internet Explorer 5.01 or higher, Netscape Communicator 4.5-4.8, Netscape 6.1, 6.2 or 7.

The steps to access application materials are as follows:

1. Download and install PureEdge Viewer, a small, free program that provides access to the grant application. See http://www.grants.gov/resources/download_software.jsp#pureedge.
2. The application package must be obtained via Grants.gov, go to <http://www.grants.gov>, click on “Apply for Grants” in the left-hand column, click on “**Step 1: Download a Grant Application Package and Instructions**,” enter the CFDA number 10.219 or enter the funding opportunity number USDA-CSREES-BRAP-000327 in the appropriate box and click “Download Package.” From the search results, click “Download” to access the application package.

Contained within the application package is the “[CSREES Grants.gov Application Guide: A Guide for Preparation and Submission of CSREES Applications via Grants.gov](#).” This Guide contains an introduction and general Grants.gov instructions, information about how to use a Grant Application Package in Grants.gov, and instructions on how to complete the application forms.

If assistance is needed to access the application package (e.g., downloading or navigating PureEdge forms, using PureEdge with a Macintosh computer), refer to resources available on the Grants.gov Web site first (<http://grants.gov/>). Grants.gov assistance is also available as follows:

- Grants.gov customer support
Toll Free: 1-800-518-4726
Business Hours: M-F 7:00 am – 9 pm Eastern Standard Time
Email: support@grants.gov

Note: If immediate assistance is needed from Grants.gov, it is suggested they be contacted by phone rather than by email. See <http://www.csrees.usda.gov/funding/electronic.html> for additional resources for applying electronically.

B. Content and Form of Application Submission

Electronic applications should be prepared following Part V and VI of the document entitled “[A Guide for Preparation and Submission of CSREES Applications via Grants.gov.](#)” This guide is part of the corresponding application package (see Section A. of this Part). The following is **additional information** needed in order to prepare an application in response to this RFA. If there is discrepancy between the two documents, the information contained in this RFA is overriding.

Note the attachment requirements (e.g., portable document format) in Part III Section 3. of the Guide.

1. R&R Other Project Information Form

a. Project Summary/Abstract (Field 6. on the Form). The summary should also include the relevance of the project to the goals of BRAG.

b. Project Narrative (Field 7. on the Form).

PLEASE NOTE: The Project Narrative shall not exceed eighteen (18) pages of written text including figures and tables either single- or double-spaced. Use an easily readable font face (e.g., Geneva, Helvetica, Times Roman). This maximum has been established to ensure fair and equitable competition. The Project Narrative must include all of the following:

(1) Introduction. A clear statement of the long-term goal(s) and supporting objectives of the proposed project should preface the project description. The most significant published work in the field under consideration, including the work of key project personnel on the current application, should be reviewed. The current status of research in the particular scientific field also should be described.

(2) Progress report. Renewal applications and resubmitted renewal applications (as described in Part II.,B.) should include a clearly marked performance report describing results to date from the previous award. This section should contain the following information: (1) a comparison of actual accomplishments with the goals established for the previous award; (2) the reasons established goals were not met, if applicable; and (3) a listing of any publications resulting from the previous award. Copies of reprints or preprints may be included in the Appendices to Project Narrative portion of the submission.

(3) Rationale and significance. Present concisely the rationale behind the proposed project. The objectives' specific relationship and relevance to the program area in which an application is submitted (see Part I, C.) and the objectives' specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly. Any novel ideas or contributions that the proposed project offers should also be discussed in this section.

(4) Experimental plan. The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must

include: (1) a description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed; (2) techniques to be used in carrying out the proposed project, including the feasibility of the techniques; (3) results expected; (4) means by which experimental data will be analyzed or interpreted; (5) pitfalls that may be encountered; (6) limitations to proposed procedures; and (7) a tentative schedule for conducting major steps involved in these investigations and/or experiments.

In the experimental plan, the applicant must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a particular phase of the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

c. Bibliography and References Cited (Field 8. on the Form).

All work cited, including that of key personnel, should be referenced in this section of the application.

d. Other Attachments (Field 11. on the Form).

(1) Response to Previous Review. This requirement only applies to “Resubmitted Applications” and “Resubmitted Renewal Applications” as described under Part II, B., “Types of Applications.” PDs must respond to the previous review panel summary on no more than one page, titled “RESPONSE TO PREVIOUS REVIEW.”

(2) Cooperation and Institutional Units Involved. Cooperative, multi-institutional and multidisciplinary applications are encouraged. Where applicable, identify each institutional unit contributing to the project and designate the lead institution or institutional unit. Clearly define the programmatic roles, responsibilities and budget for each institutional partner.

(3) Appendices to Project Narrative. Appendices to the Project Narrative are allowed if they are directly germane to the proposed project. The addition of appendices should not be used to circumvent the text and/or figures and tables page limitations.

(4) Collaborative Arrangements. If it will be necessary to enter into formal consulting or collaborative arrangements with others, such arrangements should be fully explained and justified. If the consultant(s) or collaborator(s) are known at the time of application, a vitae or resume should be provided. In addition, evidence (e.g., letter of support) should be provided that the collaborators involved have agreed to render these services. The applicant also will be required to provide additional information on consultants and collaborators in the budget portion of the application.

2. CSREES Supplemental Information Form

a. Program Code (Field 2. on the Form). Enter the program code name “**Biotechnology Risk Assessment**” and the program code enter “**HX**”.

b. Conflict of Interest List (Field 8. on the Form). A conflict of interest list is required under this program.

C. Submission Date and Time

Instructions for submitting an application are included in Part IV, Section 1.9 of the CSREES Grants.gov Application Guide.

Applications must be received by Grants.gov by COB on **February 15, 2007 (5:00 p.m. Eastern Time)**. Applications received after this deadline will normally not be considered for funding.

The receipt of all applications will be acknowledged by e-mail. Therefore, applicants are strongly encouraged to provide accurate e-mail addresses, where designated, on the SF-424 R&R Application for Federal Assistance.

If the AR has not received a confirmation message from CSREES within 30 days of submission of the application, please contact the Program Contact identified in Part VII of the applicable RFA and request the proposal number assigned to the application. **Failure to do so may result in the application not being considered for funding by the peer review panel or a delay in the issuance of an award. Once the application has been assigned a proposal number, this number should be cited on all future correspondence.**

D. Funding Restrictions

Under the BRAG program, the use of grant funds to plan, acquire, or construct a building or facility is not allowed. With prior approval, in accordance with the cost principles set forth in OMB Circular No. A-21, some grant funds may be used for minor alterations, renovations, or repairs deemed necessary to retrofit existing teaching spaces in order to carry out a funded project. However, requests to use grant funds for such purposes must demonstrate that such expenditures are incidental to the major purpose for which a grant is made.

Section 709 of the FY 2006 Consolidated Appropriations Act (Public Law 109-97) limits indirect costs to 20 percent of the total Federal funds provided under each award. Therefore, when preparing budgets, applicants should limit their requests for recovery of indirect costs to the lesser of their institution's official negotiated indirect cost rate or the equivalent of 20 percent of total Federal funds awarded. Another method of calculating the maximum allowable is 25 percent of the total direct costs. Therefore, when preparing budgets, applicants should limit their requests for recovery of indirect costs to the lesser of their institution's official negotiated indirect cost rate or the equivalent of 20 percent of total Federal funds awarded. Another method of calculating the maximum allowable is 25 percent of the total direct costs. Please note that if the FY 2007 Appropriations Act contains a different indirect cost limitation CSREES will contact each successful applicant to apply the correct rate prior to the award of a grant.

E. Other Submission Requirements

The applicant should follow the submission requirements noted in the document entitled “A Guide for Preparation and Submission of CSREES Applications via Grants.gov.”

PART V—APPLICATION REVIEW REQUIREMENTS

A. General

Each application will be evaluated in a 2-part process. First, each application will be screened to ensure that it meets the administrative requirements as set forth in this RFA. Second, applications that meet these requirements will be technically evaluated by a review panel.

Reviewers will be selected based upon training and experience in relevant scientific, extension, or education fields, taking into account the following factors: (a) The level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers other experts (e.g., producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs; (d) the need to include as reviewers experts from a variety of organizational types (e.g., colleges, universities, industry, state and Federal agencies, private profit and non-profit organizations) and geographic locations; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness to producers and the general public of each application.

B. Evaluation Criteria

The evaluation criteria identified in [7 CFR 3415.15](#) will be used to review all applications submitted in response to this RFA except applications that seek funding for conferences.

Applications that seek funding for scientific research conferences will be evaluated based on the following criteria:

1. Relevance and timeliness of topics and selection of appropriate speakers;
2. General format of the conference, especially with regard to its appropriateness for fostering scientific exchange and/or public understanding;
3. Provisions for wide participation from the scientific and regulatory community and others, as appropriate;
4. Qualifications of the organizing committee;
5. Appropriateness of the budget requested; and
6. Qualifications of project personnel.

C. Conflicts of Interest and Confidentiality

During the peer evaluation process, extreme care will be taken to prevent any actual or perceived conflicts of interest that may impact review or evaluation. For the purpose of determining conflicts of interest, the academic and administrative autonomy of an institution shall be determined by reference to the current Higher Education Directory, published by Higher Education Publications, Inc., 6400 Arlington Boulevard, Suite 648, Falls Church, Virginia 22042. Phone: (703) 532-2300. Web site: <http://www.hepinc.com>.

Names of submitting institutions and individuals, as well as application content and peer evaluations, will be kept confidential, except to those involved in the review process, to the extent permitted by law. In addition, the identities of peer reviewers will remain confidential throughout the entire review process. Therefore, the names of the reviewers will not be released to applicants.

D. Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one time basis, with updates on an as needed basis, as part of the responsibility determination prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another CSREES program. CSREES will provide copies of forms recommended for use in fulfilling these requirements as part of the preaward process. Although an applicant may be eligible based on its status as one of these entities, there are factors which may exclude an applicant from receiving Federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual involved or a determination that an applicant is not responsible based on submitted organizational management information).

PART VI—AWARD ADMINISTRATION

A. General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the awarding official of CSREES as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by CSREES under this RFA shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015 and 3019 of 7 CFR).

B. Award Notice

The award document will provide pertinent instructions and information including, at a minimum, the following:

- (1) Legal name and address of performing organization or institution to whom the Administrator has issued an award under the terms of this request for applications;
- (2) Title of project;
- (3) Name(s) and institution(s) of PDs chosen to direct and control approved activities;
- (4) Identifying award number assigned by the Department;
- (5) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;
- (6) Total amount of Departmental financial assistance approved by the Administrator during the project period;
- (7) Legal authority(ies) under which the award is issued;
- (8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
- (9) Applicable award terms and conditions (see <http://www.csrees.usda.gov/business/awards/awardterms.html> to view CSREES award terms and conditions);

(10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and

(11) Other information or provisions deemed necessary by CSREES to carry out its respective awarding activities or to accomplish the purpose of a particular award.

C. Administrative and National Policy Requirements

Several Federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These include, but are not limited to:

7 CFR Part 1, subpart A—USDA implementation of the Freedom of Information Act.

7 CFR Part 3—USDA implementation of OMB Circular No. A-129 regarding debt collection.

7 CFR Part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR Part 331 and 9 CFR Part 121—USDA implementation of the Agricultural Bioterrorism Protection Act of 2002.

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21 and A-122, now codified at 2 CFR Parts 220 and 230) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR Part 3017—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and 7 CFR Part 3021—Governmentwide Requirements for Drug Free Workplace (Grants).

7 CFR Part 3018—USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR Part 3019—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR Part 3052—USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Non profit Organizations.

7 CFR Part 3407—CSREES procedures to implement the National Environmental Policy Act of 1969, as amended.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute) —prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq. —Bayh Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR Part 401).

It is the responsibility of the applicant to request clarification on regulatory requirements from the USDA's Animal and Plant Health Inspection Service.

If the proposed research falls under the authority or oversight of the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA) or the Federal Food, Drug and Cosmetic Act (FFDCA), it is the responsibility of the applicant to ensure that the appropriate statutory and regulatory requirements are met with respect to research conducted as part of the grant proposal. The applicant must contact the U.S. Environmental Protection Agency and/or Food and Drug Administration as appropriate, to determine any regulatory requirements that may arise as a result of the proposed research.

USDA APHIS BRS contact - <http://www.aphis.usda.gov/subjects/biotechnology/>

U.S. EPA BPPD contact - <http://www.epa.gov/pesticides/biopesticides/index.htm>

FDA contact - <http://www.fda.gov/oc/industry/default.htm>

coordinated framework site - <http://usbiotechreg.nbii.gov/>

D. Expected Program Outputs and Reporting Requirements

Project Directors are expected to attend a one- to two-day Project Directors Conference in the metro Washington, D.C. area. Reasonable travel expenses may be claimed as part of the project budget.

Awardees are required to submit initial project information and annual and summary reports to CSREES' Current Research Information System (CRIS). The CRIS database contains narrative project information, progress/impact statements, and final technical reports that are made available to the public. For applications recommended for funding, instructions on preparation and submission of project documentation will be provided to the applicant by the agency contact. Documentation must be submitted to CRIS before CSREES funds will be released. Project reports will be requested by the CRIS office when required. For more information about CRIS, visit <http://cris.csrees.usda.gov/>.

Any additional reporting requirements will be identified in the terms and conditions of the award (see Part VI, B.9. for a link to view CSREES award terms and conditions).

PART VII—AGENCY CONTACTS

Applicants and other interested parties are encouraged to contact Dr. Daniel Jones; Program Director, Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2220; 1400 Independence Avenue, SW; Washington, DC 20250-2220; telephone: (202) 401-6854; fax: (202) 401-1602; e-mail: djones@csrees.usda.gov; Dr. Chris Wozniak, Program Director, Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2220; 1400 Independence Avenue, SW; Washington, DC 20250-2220; telephone: (202) 401-6020; fax: (202) 401-6156; e-mail: cwozniak@csrees.usda.gov; or Dr. Kay Simmons; National Program Leader, Crop Production and Protection; Agricultural Research Service; U.S. Department of Agriculture; George Washington Carver Center, Room 4-2210; 5601 Sunnyside Avenue; Beltsville, MD 20705-5139; telephone: (301) 504-5560; fax: (301) 504-6191; e-mail: kay.simmons@ars.usda.gov.

PART VIII—OTHER INFORMATION

A. Access to Review Information

Copies of reviews, not including the identity of reviewers, and a summary of the panel comments will be sent to the applicant PD after the review process has been completed.

B. Use of Funds; Changes

1. Delegation of Fiscal Responsibility

Unless the terms and conditions of the award state otherwise, the awardee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of award funds.

2. Changes in Project Plans

a. The permissible changes by the awardee, PD(s), or other key project personnel in the approved project shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the awardee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.

b. Changes in approved goals or objectives shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

c. Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes.

d. Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the awardee and approved in writing by the ADO prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the award.

e. The project period may be extended by CSREES without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed five years. Any extension of time shall be conditioned upon prior request by the awardee and approval in writing by the ADO, unless prescribed otherwise in the terms and conditions of award.

f. Changes in Approved Budget: Unless stated otherwise in the terms and conditions of award, changes in an approved budget must be requested by the awardee and approved in writing by the ADO prior to instituting such changes if the revision will involve transfers or expenditures of

amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or award.

C. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of the record of CSREES transactions, available to the public upon specific request. Information that the Secretary determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the application. The original copy of an application that does not result in an award will be retained by the Agency for a period of three years. Other copies will be destroyed. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn at any time prior to the final action thereon.

D. Regulatory Information

For the reasons set forth in the final Rule related Notice to 7 CFR part 3015, subpart V (48 FR 29114, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0039.

E. Definitions

For the purpose of this program, the following definitions are applicable:

Administrator means the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) and any other officer or employee of the Department to whom the authority involved is delegated.

Authorized departmental officer means the Secretary or any employee of the Department who has the authority to issue or modify grant instruments on behalf of the Secretary.

Authorized representative means the president, director, or chief executive officer or other designated official of the applicant organization who has the authority to commit the resources of the organization.

Biotechnology means any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included.

Budget period means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

Cash contributions means the applicants cash outlay, including the outlay of money contributed to the applicant by non-Federal third parties.

Department or USDA means the United States Department of Agriculture.

Education activity means formal classroom instruction, laboratory instruction, and practicum experience in the food and agricultural sciences and other related matters such as faculty development, student recruitment and services, curriculum development, instructional materials and equipment, and innovative teaching methodologies.

Extension activity means an act or process that delivers science-based knowledge and informal educational programs to people, enabling them to make practical decisions.

Grant means the award by the Secretary of funds to an eligible organization or individual to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to accomplish the purpose of the program as identified in these guidelines.

Grantee means an organization designated in the grant award document as the responsible legal entity to which a grant is awarded.

Matching means that portion of allowable project costs not borne by the Federal Government, including the value of in-kind contributions.

Peer review means an evaluation of a proposed project for scientific or technical quality and relevance performed by experts with the scientific knowledge and technical skills to conduct the proposed work or to give expert advice on the merits of a proposal. and management of the project.

Prior approval means written approval evidencing prior consent by an authorized departmental officer as defined above.

Project means the particular activity within the scope of the program supported by a grant award.

Project director means the single individual designated in the grant application and approved by the Secretary who is responsible for the direction and management of the project.

Project period means the period, as stated in the award document, during which Federal sponsorship begins and ends.

Research activity means a scientific investigation or inquiry that results in the generation of knowledge.

Secretary means the Secretary of Agriculture and any other officer or employee of the Department to whom the authority involved is delegated.

F. CSREES' Grants.gov Implementation Plans

CSREES is continuing to develop its capacity to exchange proposal and grant data electronically with its grantees through [Grants.gov](http://www.grants.gov) and to process, review, and award proposals and grants electronically.

In Fiscal Year (FY) 2006, CSREES offered an electronic application option for select grant programs and partnered with five institutions to use Grants.gov Apply. CSREES utilized the SF-424 R&R (Research and Related) forms package (see 70 FR 9656, published in the Federal Register on February 28, 2005) along with CSREES Agency-specific forms and instructions to receive the electronic applications. These pilot activities were successful and provided lessons for applicants and CSREES.

As a result, for the FY 2007 (October 1, 2006-September 30, 2007) cycle, CSREES is requiring electronic submission through Grants.gov for some programs while providing a Grants.gov option for others. Please visit <http://www.csrees.usda.gov/funding/fy07changes.html> for information about FY 2007 submission requirements by program. For more information about CSREES' Grants.gov plans, including important announcements, program implementation, and detailed requirements, see the CSREES' web site, http://www.csrees.usda.gov/business/other_links/egov/egov.html. The information on these web sites will be updated as appropriate. It is suggested that the sites be visited periodically for important updates.

G. DUNS Number

A Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a unique nine-digit sequence recognized as the universal standard for identifying and keeping track of over 70 million businesses worldwide. A Federal Register notice of final policy issuance (68 FR 38402) requires a DUNS number in every application (i.e., hard copy and electronic) for a grant or cooperative agreement (except applications from individuals) submitted on or after October 1, 2003. Therefore, project directors should contact an AR to obtain the DUNS number or have the AR begin the steps needed to obtain one.

For information about how to obtain a DUNS number go to <http://www.grants.gov/RequestaDUNS>. Please note that the registration may take up to 14 business days to complete.